#15

Status: Open.

Purpose: To pursue with the Health Care Financing Administration and the Social Security Administration feasible methods to include racial and ethnic identifiers in the Medicare data files.

Contact Person for More Information: Substantive program information as well as summaries of the meeting and a roster of committee members may be obtained from Gail F. Fisher, Ph.D., Executive Secretary, NCVHS, NCHS, room 1100, Presidential Building, 6525 Belcrest Road, Hyattsville, Maryland 20782, telephone 301/436-7050 or FTS 436-7050.

Dated: April 30, 1991.

Elvin Hilyer,

Associate Director for Policy Coordination Centers for Disease Control.

[FR Doc. 91-10582 Filed 5-3-91; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

Formalin for Use in the Treatment of Penaeid Shrimp Diseases; Data; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of safety, effectiveness, and environmental data to be used in support of a new animal drug application (NADA) for use of formalin to treat penaeid shrimp diseases. The data, contained in Public Master File (PMF) 3543, were compiled under the U.S. Department of the Interior and the U.S. Department of Agriculture Interregional Research Project No. 4 (IR-4), a national agricultural programs for obtaining clearances for use of agricultural products for minor or special uses.

ADDRESSES: Submit NADA's for use of formalin to treat penaeid shrimp diseases to the Document Control Section (HFV-199), Center for Veterinary Medicine, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Larry D. Rollins, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3410.

SUPPLEMENTARY INFORMATION: The use of formalin to treat diseases of penaeid shrimp in confinement is a new animal drug use under section 201(w) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(w)). As a new animal drug, it is subject to section 512 of the act (21 U.S.C. 360b) requiring that its uses be the subject of an approved NADA.

The University of Arizona, Tucson, AZ 85721, has provided data and information to demonstrate effectiveness, safety to the target animal, and tissue residue depletion for use of 50 to 100 parts per million (ppm) formalin for up to 4 hours or 25 ppm continuously for control of external protozoan parasites (*Bodo* spp., *Epistylis* spp., and *Zoothamnium* spp.) on penaeid shrimp. The University of California IR-4 Project, Western Region, Davis, CA 95616, provided an environmental assessment of possible impacts at the site of use of the animal drug product. The data and information are contained in PMF 3543.

Sponsors of NADA's or supplemental NADA's may reference the PMF without further authorization to support an application's approval. An NADA or supplemental NADA should include, in addition to references to the PMF, drug labeling, and other information needed for approval, such as human food safety data, information and data concerning manufacturing methods, facilities, and controls, and information addressing the potential environmental impacts of the manufacturing process. Persons desiring more information concerning the PMF or requirements for approval of an NADA may contact Larry D. Rollins (address above).

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information in PMF 3543, submitted to support approval of an NADA, may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 30857, from 9 a.m. to 4 p.m., Monday through Friday.

Dated: April 29, 1991.

Gerald B. Guest,

Director, Center for Veterinary Medicine.

[FR Doc. 91-10587 Filed 5-3-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91E-0124]

Determination of Regulatory Review Period for Purposes of Patent Extension; Ganite™

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Ganite™ and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two period of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Ganite. Ganite (gallium nitrate injection) is indicated for the treatment of clearly symptomatic cancer-related hypercalcemia that has not responded to adequate hydration. Subsequent to this approval, the Patent and Trademark Office received a patent

term restoration application for Ganite (U.S. Patent No. 4,529,593) from the Sloan-Kettering Institute for Cancer Research, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated April 2, 1991, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Ganite represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Ganite is 6,279 days. Of this time, 5,610 days occurred during the testing phase of the regulatory review period, while 669 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* November 10, 1973. FDA has verified the applicant's claim that the date the investigational new drug (IND) application became effective was November 10, 1973.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* March 20, 1989. The applicant claims March 17, 1989, as the date the new drug application (NDA 19-961) was filed. However, FDA records indicate that the NDA was received March 20, 1989.

3. *The date the application was approved:* January 17, 1991. FDA has verified the applicant's claim that NDA 19-961 was approved January 17, 1991.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the U.S. Patent and Trademark Office applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 916 days of patent term extension.

Anyone with knowledge that any of the dates as published is incorrect may, on or before July 5, 1991, submit to the Dockets Management Branch (address above) written comments and ask for a redetermination. Furthermore, any interested person may petition FDA, on or before November 4, 1991, for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must contain sufficient facts to merit an FDA investigation. (See H. Rept. 857, part 1, 98th Cong., 2d Sess., pp. 41-42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Comments and petitions should be submitted to the Dockets Management Branch (address above) in three copies (except that individuals may submit single copies) and identified with the docket number found in brackets in the heading of this document. Comments and petitions may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 26, 1991.

Stuart L. Nightingale,

Associate Commissioner for Health Affairs.

[FR Doc. 91-10588 Filed 5-3-91; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 91E-0117]

Determination of Regulatory Review Period for Purposes of Patent Extension; Geref®

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for Geref® and is publishing this notice of that determinaton as required by law. FDA has made the determination because of the submission of an application to the Commissioner of Patents and Trademarks, Department of Commerce, for the extension of a patent which claims that human drug product.

ADDRESSES: Written comments and petitions should be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Nancy E. Pirt, Office of Health Affairs (HFY-20), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-1382.

SUPPLEMENTARY INFORMATION: The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98-417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100-670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Commissioner of Patents and Trademarks may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA recently approved for marketing the human drug product Geref®. Geref® (sermorelin acetate) is indicated for the evaluation of the functional capacity and responsiveness of the somatotrophs of the anterior pituitary gland. Subsequent to this approval, the Patent and Trademark Office received a patent term restoration application for Geref® (U.S. Patent No. 4,703,035) from The Salk Institute for Biological Studies, and the Patent and Trademark Office requested FDA's assistance in determining this patent's eligibility for patent term restoration. FDA, in a letter dated March 26, 1991, advised the Patent and Trademark Office that this human drug product had undergone a regulatory review period and that the approval of Geref® represented the first commercial marketing of the product. Shortly thereafter, the Patent and Trademark Office requested that the FDA determine the product's regulatory review period.

FDA has determined that the applicable regulatory review period for Geref® is 1,166 days. Of this time, 198 days occurred during the testing phase of the regulatory review period, while 968 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act became effective:* October 21, 1987. The applicant claims August 31, 1987, as the date the investigational new drug (IND) application became effective. However, FDA records indicate that the IND effective date was October 21, 1987, after a clinical hold was lifted.

2. *The date the application was initially submitted with respect to the human drug product under section 505(b) of the Federal Food, Drug, and Cosmetic Act:* May 5, 1988. The applicant claims April 29, 1988, as the